



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/938,294      | 08/24/2001  | Gregory J. Hinkle    | 16517.253           | 1056             |

7590

07/16/2003

Lawrence M. Lavin, Jr.  
Patent Department, E2NA; Monsanto Company  
800 N. Lindbergh Boulevard  
St. Louis, MO 63167

EXAMINER

BUI, PHUONG T

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 07/16/2003

6

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
**09/938,294**

Applicant(s)  
**Hinkle et al.**

Examiner  
**Phuong Bui**

Art Unit  
**1638**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on May 2, 2003
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above, claim(s) 6, 7, and 11-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 8-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4 6) ☐ Other:

## **DETAILED ACTION**

### ***Restriction election***

1. The Office acknowledges the receipt of Applicant's restriction election, Paper No. 7, filed May 2, 2003. Applicant elects Group IB, claims 1-5, 8-10 and SEQ ID NO:2 encoding SEQ ID NO:45, with traverse, stating that it would not be a serious burden to the Office to examine the entire application, and that at least ten nucleotide sequences should be examined. Applicant's traversal is unpersuasive for the following reasons: the nucleotide and protein sequences have been shown to be patentably distinct in the restriction requirement. Furthermore, the nucleotide sequences have also been shown to be patentably distinct from each other, for reasons of record. While an Examiner may have had the option to examine up to ten sequences in the past, Office resources can no longer support such a search, and it would create a serious burden to the Office to examine ten sequences per application. Furthermore, while a search of the prior art for one invention may overlap with the prior art of another invention, the searches are not coextensive of each other, and thus would create a burden to the Office to examine the inventions together. Also, a sequence search of the databases for one sequence does not necessarily uncover other claimed sequences. Accordingly, this restriction is maintained and made FINAL. Claims 1-13 are pending. Claims 6-7 and 11-13 are nonelected. Claims 1-5 and 8-10 (SEQ ID NO:2 encoding SEQ ID NO:45) are examined in the instant application.

### ***Specification***

2. The specification is objected to because of the following: current US patent policy does not permit the use of hyperlinks in the specification. Such links are directed to an Internet site, the contents of which are subject to change without notice. Therefore, the potential for inclusion of new matter would be a constant problem. See page 10, for example. All hyperlinks must be deleted as appropriate. Correction is required.

***Sequence Listing***

3. Applicant's CRF and paper sequence listing have been entered.

***Information Disclosure Statement***

4. An initialed and dated copy of Applicant's IDS form 1449, Paper No. 4, is attached to the instant Office action.

***Claim Objections***

5. Claims 1-3 and 8 are objected to for reciting nonelected inventions. Correction is required.

***Claim Rejections - 35 USC § 101 Utility***

6. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claims 1-5 and 8-10 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, substantial asserted utility or a well established utility. The claims are directed to nucleotide sequences and transformed plants or organisms containing said sequences. The specification disclosed the claimed invention can be used "to develop

nutritionally and agriculturally enhanced crops and products” and “aid gene expression studies that allow the dissection and elucidation of commercially useful traits” (p. 2, lines 1-6). The specification does not disclose any trait the claimed invention can be used to enhance, or how the claimed invention can be used to enhance such trait. Under current utility guidelines, the claimed invention lacks specific and substantial asserted utility for the following reasons. First of all, if a plant gene affects plant growth or development in any way, positively or adversely, then the gene is directly or indirectly involved in “nutritionally and agriculturally enhanced crops and products”. Thus this asserted utility is not specific to any particular class or group of plant genes, as most if not all plant genes would fulfill this asserted utility. Secondly, the claimed invention lacks substantial utility because a utility which requires or constitutes carrying out further research to identify or reasonably confirm a “real world” context of use is not a substantial utility.

In *Brenner v. Manson*, the court established:

“The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point--where specific benefit exists in currently available form--there is insufficient justification for permitting an applicant to engross what may prove to be a broad field.” (*Brenner v. Manson*, 383 U.S. 519 (1966)).

Thus, while commercially useful traits such as increased yields would provide substantial benefit to the public, it is unclear how one of ordinary skill in the art would be able to use SEQ ID NO:2 encoding SEQ ID NO:45 “to develop nutritionally and agriculturally enhanced crops and products” and “aid gene expression studies that allow the dissection and elucidation of commercially useful traits” as set forth in the specification. It is unclear what trait is correlated

with the claimed sequence, or how said sequence should be used to enhance said trait. Should the expression of SEQ ID NO:2 be increased, decreased or inhibited to enhance the plant's nutritional value or commercially useful trait? Which trait(s)? Accordingly, the claimed invention lacks specific and substantial utility. Note, because the claimed invention is not supported by a specific asserted utility for the reasons set forth above, credibility cannot be assessed.

In addressing well-established utility, since the claimed invention lacks asserted utility for the reasons set forth above, the claimed invention also lacks well-established utility, such as probes and primers for use in hybridization assays. While one skilled in the art can readily generate probes and primers from the claimed sequence, it is unclear how probes and primers of a gene of undisclosed function would be useful to the public. Accordingly, the claimed invention also lacks well established utility.

***Claim Rejections - 35 USC § 112, first paragraph***

8. Claims 1-5 and 8-10 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. Additionally, in claim 8, Applicant is not enabled for "fragments thereof". Because SEQ ID NO:2 is not enabled as stated above, fragments thereof are also not enabled. Applicant should note that no function is recited for the claimed fragments. Applicant does not show which region(s) of SEQ ID NO:2 should be retained in the fragments for the desired activity. Absent of further guidance as to how SEQ ID NO:2 and fragments

thereof should be used, or which region(s) of the fragments are necessary for the desired activity, one skilled in the art would not be able to make and used the claimed invention without undue experimentation.

***Claim Rejections - 35 USC § 112, second paragraph***

9. Claims 1-5 and 8-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, the definition given in the specification for “substantially purified” is circular, as Applicant uses the same word to define the word in question. On page 8, Applicant defines “substantially purified” a molecule separated from substantially all other molecules normally associated with it. Accordingly, the metes and bounds of “substantially purified” are unclear. It is suggested that Applicant delete “substantially”. All recitations of “substantially purified” in subsequent claims are also rejected.

In claim 1, it is suggested that Applicant insert “full-length” before “complements” as “complements” may read on a single base, which does not appear to be Applicant’s intention. All recitations of “complements” in subsequent claims are also rejected.

In claim 8, it is unclear what structure is desired by the recitation of “structural nucleic acid molecule”. Does Applicant mean a nucleic acid molecule encoding a structural gene?

Clarification and/or correction are required.

***Claim Rejections - 35 USC § 102***

Serial No: 09/938294

Art Unit: 1638

Page 7

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

a person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 8-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Goodman et al. (USPN 4956282 (a)). The "comprising" and "fragments thereof" without any recited function language read on a transformed plant expressing any protein of interest. Goodman teaches transformed maize and soybean expressing interferon, wherein said plant contains a plant functional promoter, structural gene and non-translated termination sequence (col. 4, ln 59, col. 2, ln. 28-33). Accordingly, Goodman anticipated the claimed invention.

***Remarks***

12. No claim is allowed. SEQ ID NO:2 encoding SEQ ID NO:45 is free of the prior art.

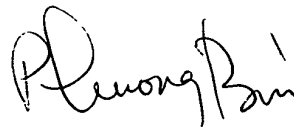
13. Papers relating to this application may be submitted to Technology Sector 1 by facsimile transmission. Papers should be faxed to Crystal Mall 1, Art Unit 1638, using fax number (703) 308-4242. All Technology Sector 1 fax machines are available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Bui whose telephone number is (703) 305-1996.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

Phuong Bui  
July 14, 2003

  
**PHUONG T. BUI**  
**PRIMARY EXAMINER**